

REMARKS

Claims 31, 34-42, and 60-63 were pending in this application. Claims 31, 37, and 38 are amended. Claim 64 is newly presented. After entry of this amendment, claims 31, 34-42, and 60-64 will be pending in this application. Applicants submit that these amendments add no new matter.

Interview Summary

Applicants would like to thank Examiner Andersen for his time and helpful suggestions during the telephonic interview of April 11, 2007. Therein, Applicants discussed with the Examiner the rejection of claim 31 in view of Ginn. However, no agreement was reached.

Amendments to the Claims

Independent claim 31 is amended to recite introducing the second free end portion of the first flexible member through the opening of a patent foramen ovale prior to introducing a hole through a septum primum. Support for this amendment is found in the application as originally filed, for example, at lines 5-7 of paragraph 4, in paragraphs 72-74, and in FIGS. 9, and 10A-C.

Independent claim 37 is amended to recite introducing at least one of said hexagonally shaped flexible members through the opening of a patent foramen ovale and contacting the at least one hexagonally shaped flexible member with a septum primum on the septum primum's left atrial side. Support for this amendment can be found in the application as originally filed, for example, at least in paragraph 16 and at lines 4-6 and 14-15 of paragraph 82.

Claim 38 is amended to recite that the method further comprises the step of providing a cutting member and introducing a hole in said septum primum. Support for this amendment can be found in the application as originally filed, for example, at lines 14-15 of paragraph 82.

Support for new claim 64 can be found in the application as originally filed, for example, at lines 6-9 of paragraph 81 and at lines 10-15 of paragraph 82.

Claim Rejections under 35 U.S.C. § 102

Claims 31, 34-35 and 60-63 stand rejected under 35 U.S.C. § 102(a) as being anticipated by U.S. Patent No. 6,702,835 to Ginn ("Ginn"). Applicants traverse the rejection to the extent it is maintained over the claims as amended.

It is well known law that in order for a claim to be anticipated, each and every element set forth in the claim must be found in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053.

Applicants submit that Ginn is an improper reference under 35 U.S.C. 102(b) at least because Ginn does not teach the steps of introducing into the heart of a patient a delivery member comprising at least a first flexible member comprising a first end portion and a second free end portion and introducing the second free end portion through the opening of a patent foramen ovale prior to introducing a hole through a septum primum, as required by Applicants' claimed invention.

Applicants submit that Ginn's device is positioned adjacent a septal opening in the first chamber of the heart via a catheter (col. 11, lines 46-55). The needle tip of the device is then advanced to pierce a flap of tissue of a septal defect and to pierce an overlapping portion of the septum wall (col. 11, lines 52-56; FIGS. 8A-B).

In contrast, Applicants' claimed invention requires introducing the second free end portion of the first flexible member through the opening of a patent foramen ovale prior to introducing a hole through a septum primum.

For argument's sake, if Ginn's device is introduced through the opening of a patent foramen ovale, in contrast to Applicants' required step of introducing Applicants' free end portion through the opening of a patent foramen ovale prior to introducing a hole in the septum, Ginn's device is not introduced through the opening of the patent foramen ovale until after the septum is punctured by Ginn's device.

Accordingly, Ginn cannot anticipate independent claim 31, or claims 34-36, 60-63 depending from claim 31 under 35 U.S.C. § 102(a). Applicants therefore respectfully request reconsideration and withdrawal of the rejection of these claims be reconsidered and withdrawn.

Claim 37 stands rejected under 35 U.S.C. § 102(a) as being anticipated by U.S. Patent No. 5,334,217 to Das (“Das”). Applicants traverse the rejection to the extent it is maintained over the claims as amended.

Claim 37 requires the steps of introducing at least one hexagonally shaped flexible member through the opening of a patent foramen ovale, contacting said at least one hexagonally shaped flexible member with a septum primum on the septum primum’s left atrial side, and withdrawing the at least one hexagonally shaped flexible member from the left atrial side.

Das teaches a septal defect closure device having a first disk and a second disk (col. 4, lines 53-54 and 62-65). Das’ device is deployed at a septal defect such that the first disk engages the distal side of the defect and the second disk is deployed on the opposite side of the septum (col. 12, lines 24-33). Das teaches that the device is permanently “anchored to the septum” to “prevent the flow of blood through the septum” so that the heart will operate normally (col. 4, lines 53-60; emphasis added). Das is silent as to the disks being withdrawn from the septal defect once deployed.

In contrast to the teachings of Das, Applicants claimed invention requires contacting at least one hexagonally shaped flexible member with a septum primum on the septum primum’s left atrial side and withdrawing the hexagonally shaped flexible member from the left atrial side.

Therefore, even if Das teaches that a hexagonally shaped disk of Das’ device contacts the septum primum on the septum primum’s left atrial side, Das fails to teach withdrawing that same hexagonally shaped flexible member from the left atrial side.

For at least this reason, Applicants believe that Das cannot anticipate independent claim 37 under 35 U.S.C. § 102. Accordingly, Applicants respectfully request that the rejection of claim 37 be reconsidered and withdrawn.

Claim Rejections under 35 U.S.C. § 103

Claims 38-41 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Das in view of Ginn.

It is a well known principle of law that to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981.

Claims 38-41 are dependent from claim 37. As previously discussed, claim 37 is patentable in view of Das because Das fails to disclose each and every limitation of claim 37. Applicants submit that claims 38-41 are therefore patentable at least for the same reasons that claim 37 is patentable. Further, Ginn fails to remedy the deficiencies of Das as described above. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 38-41 under 35 U.S.C. § 103(a).

Claim 36 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Ginn in view of U.S. Patent No. 5,749,895 to Sawyer ("Sawyer").

Claim 36 is dependent from claim 31. As previously discussed, claim 31 is patentable in view of Ginn because Ginn fails to disclose each and every limitation of claim 31. Applicants submit that claim 36 is therefore patentable at least for the same reasons that claim 31 is patentable. Further, Sawyer fails to remedy the deficiencies of Ginn. In fact, Sawyer teaches joining tissues with the aid of a patch, *e.g.*, a collagen patch. The patch is contacted with the tissues and heat is applied to join the tissues (col. 2, lines 39-55). Sawyer does not teach treating a patent foramen ovale. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 36 under 35 U.S.C. § 103(a).

Claim 42 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Das in view of Ginn and further in view of Sawyer.

Claim 42 is dependent from claim 37. As previously discussed, claim 37 is patentable in view of Das because Das fails to disclose each and every limitation of claim 37. Applicants submit that claim 42 is therefore patentable at least for the same reasons that claim 37 is patentable. Further, neither Ginn nor Sawyer (discussed above) remedies the deficiencies of Das. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 42 under 35 U.S.C. § 103(a).

CONCLUSION


Applicants submit that the currently pending claims are in condition for allowance. The Examiner is invited to telephone the undersigned attorney to discuss and outstanding issues.

Respectfully submitted,

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